

DOCKET NO.: I0248.70012US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Agents: Barbara P. Wallner and Glenn T. Miller
Serial No.: 09/578,363
Conf. No.: 6092
Filed: May 25, 2000
U.S. Patent No.: 6,890,904 B1
Date of Patent: May 10, 2005
For: ANTI-TUMOR AGENTS
Examiner: Jeffrey E. Russel
Art Unit: 1654

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Attention: Certificate of Correction Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 26th, 2005.

Michelle M. Quinn

Attention: Certificate of Correction Branch

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Request for Certificate of Correction
- Certificate of Correction
- Copy of pages of U.S. Patent 6,890,904 B1 with corrections marked in red
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

No check is enclosed. If any additional fees are required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

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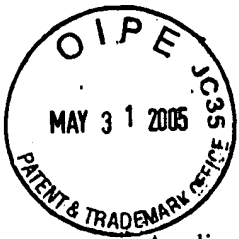
Docket No. I0248.70012US00

Date: May 26, 2005

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Commissioner for Patents
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Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 C.F.R. § 1.322

Sir:

Applicant respectfully requests the correction of errors in the claims found in the printing of U.S. Patent 6,890,904 B1.

Remarks

Applicant encloses herewith a copy of the error-containing pages from U.S. Patent 6,890,904 B1, with the errors marked in red. These errors are errors on the part of the Patent Office, and accordingly no fee is believed to be due.

Applicant respectfully requests a Certificate of Correction for the errors outlined herein.

Respectfully submitted,

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : US 6,890,904 B1

DATED : May 10, 2005

INVENTOR(S): Wallner et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 35, column 38, line 11, delete "." and insert -- , --.

In claim 39, column 38, line 35, delete "hydroxyurea," and insert -- Hydroxyurea, --.

In claim 39, column 38, line 36, delete "Interferon-a2a, Interferon-a2b," and insert -- Interferon- α 2a, Interferon- α 2b, --.

In claim 42, column 38, line 59, delete "Interferon-an3," and insert -- Interferon- α n3, --.

In claim 46, column 39, line 17, delete "Interferon α 3," and insert -- Interferon- α n3, --.

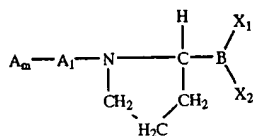
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PATENT NO. US 6,890,904 B1

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37

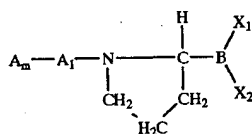
compound, and an agent, in an amount effective to inhibit the proliferation, wherein the agent is a compound of Formula II



wherein m is an integer between 0 and 10, inclusive; A and A₁ are L- or D-amino acid residues; and each X₁ and X₂ is independently a hydroxyl group or a group capable of being hydrolyzed to a hydroxyl group in aqueous solution at physiological pH, and wherein the condition is further characterized by the presence of reactive stromal fibroblasts.

22. A method for treating a subject having a condition characterized by an abnormal mammalian cell proliferation, comprising:

administering to a subject in need of such treatment, a compound selected from the group consisting of an anti-angiogenic compound and an anti-cancer compound, and an agent, in an amount effective to inhibit the proliferation, wherein the agent is a compound of Formula II



Hydroxyurea

wherein m is an integer between 0 and 10, inclusive; A and A₁ are L- or D-amino acid residues; and each X₁ and X₂ is independently a hydroxyl group or a group capable of being hydrolyzed to a hydroxyl group in aqueous solution at physiological pH, and wherein the condition is selected from the group consisting of bone and connective tissue sarcomas.

23. The method of claim 1, wherein m in Formula III is zero.

24. The method of claim 23, wherein A₁ is selected from the group consisting of valine, lysine, proline and alanine.

25. The method of claim 1, wherein A and A₁ are L- or D-isomers of naturally occurring amino acid residues.

26. The method of claim 17, wherein m in Formula III is zero.

27. The method of claim 26, wherein A₁ is selected from the group consisting of valine, lysine, proline, and alanine.

28. The method of claim 17, wherein A and A₁ are L- or D-isomers of naturally occurring amino acid residues.

29. The pharmaceutical preparation of claim 19, wherein m in Formula III is zero.

30. The pharmaceutical preparation of claim 29, wherein A₁ is selected from the group consisting of valine, lysine, proline and alanine.

31. The pharmaceutical preparation of claim 19, wherein A and A₁ are L- or D- isomers of naturally occurring amino acid residues.

32. The pharmaceutical preparation of claim 20, wherein m in Formula III is zero.

33. The pharmaceutical preparation of claim 32, wherein A₁ is selected from the group consisting of valine, lysine, proline, and alanine.

34. The pharmaceutical preparation of claim 20, wherein A and A₁ are L- or D- isomers of naturally occurring amino acid residues.

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35. The method of claim 12, wherein the anti-cancer compound is Aldesleukin, Asparaginase, Bleomycin Sulfate, Carboplatin, Chlorambucil, Cisplatin, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine, Dactinomycin, Daunorubicin hydrochloride, Docetaxel, Doxorubicin, Doxorubicin hydrochloride, Epirubicin hydrochloride, Etoposide, Etoposide phosphate, Floxuridine, Fludarabine, Fludarabine phosphate, Fluorouracil, Gemcitabine, Gemcitabine hydrochloride, Hydroxyurea, Idarubicin Hydrochloride, Ifosfamide, Interferons, Interferon-α2a, Interferon-α2b, Interferon-αn3, Interferon-γ1b, Interleukins, Irinotecan, Mechlorethamine hydrochloride, Melphalan, Mercaptopurine, Methotrexate, Methotrexate sodium, Mitomycin, Mitoxantrone, Mitoxantrone hydrochloride, Paclitaxel, Pegaspargase, Pentostatin, Prednimustine, Porfimer sodium, Procarbazine Hydrochloride, Taxotere, Teniposide, Topotecan Hydrochloride, Vinblastine Sulfate, Vincristine Sulfate or Vinorelbine tartrate.

36. The method of claim 1, wherein the agent is administered in combination with an anti-angiogenic compound.

37. The method of claim 36, wherein the anti-angiogenic compound is angiostatin or endostatin.

38. The method of claim 18, wherein the anti-angiogenic compound is angiostatin or endostatin.

39. The pharmaceutical preparation of claim 19, wherein the anti-cancer compound is Aldesleukin, Asparaginase, Bleomycin Sulfate, Carboplatin, Chlorambucil, Cisplatin, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine, Dactinomycin, Daunorubicin hydrochloride, Docetaxel, Doxorubicin, Doxorubicin hydrochloride, Epirubicin hydrochloride, Etoposide, Etoposide phosphate, Floxuridine, Fludarabine, Fludarabine phosphate, Fluorouracil, Gemcitabine, Gemcitabine hydrochloride, Hydroxyurea, Idarubicin Hydrochloride, Ifosfamide, Interferons, Interferon-α2a, Interferon-α2b, Interferon-αn3, Interferon-γ1b, Interleukins, Irinotecan, Mechlorethamine hydrochloride, Melphalan, Mercaptopurine, Methotrexate, Methotrexate sodium, Mitomycin, Mitoxantrone, Mitoxantrone hydrochloride, Paclitaxel, Pegaspargase, Pentostatin, Prednimustine, Porfimer sodium, Procarbazine Hydrochloride, Taxotere, Teniposide, Topotecan Hydrochloride, Vinblastine Sulfate, Vincristine Sulfate or Vinorelbine tartrate.

40. The pharmaceutical preparation of claim 20, wherein the anti-angiogenic compound is angiostatin or endostatin.

41. The method of claim 21, wherein the agent is administered in combination with an anti-cancer compound.

42. The method of claim 41, wherein the anti-cancer compound is Aldesleukin, Asparaginase, Bleomycin Sulfate, Carboplatin, Chlorambucil, Cisplatin, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine, Dactinomycin, Daunorubicin hydrochloride, Docetaxel, Doxorubicin, Doxorubicin hydrochloride, Epirubicin hydrochloride, Etoposide, Etoposide phosphate, Floxuridine, Fludarabine, Fludarabine phosphate, Fluorouracil, Gemcitabine, Gemcitabine hydrochloride, Hydroxyurea, Idarubicin Hydrochloride, Ifosfamide, Interferons, Interferon-α2a, Interferon-α2b, Interferon-αn3, Interferon-γ1b, Interleukins, Irinotecan, Mechlorethamine hydrochloride, Melphalan, Mercaptopurine, Methotrexate, Methotrexate sodium, Mitomycin, Mitoxantrone, Mitoxantrone hydrochloride, Paclitaxel, Pegaspargase, Pentostatin, Prednimustine, Porfimer sodium, Procarbazine Hydrochloride, Taxotere, Teniposide, Topotecan Hydrochloride, Vinblastine Sulfate, Vincristine Sulfate or Vinorelbine tartrate.

Interferon-α2a
Interferon-α2b

Interferon-αn3

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43. The method of claim 21, wherein the agent is administered in combination with an anti-angiogenesis compound.

44. The method of claim 43, wherein the anti-angiogenic compound is angiostatin or endostatin.

45. The method of claim 22, wherein the agent is administered in combination with an anti-cancer compound.

46. The method of claim 45, wherein the anti-cancer compound is Aldesleukin, Asparaginase, Bleomycin Sulfate, Carboplatin, Chlorambucil, Cisplatin, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine, Dactinomycin, Daunorubicin hydrochloride, Docetaxel, Doxorubicin, Doxorubicin hydrochloride, Epirubicin hydrochloride, Etoposide, Etoposide phosphate, Floxuridine, Fludarabine, Fludarabine phosphate, Fluorouracil, Gemcitabine, Gemcitabine hydrochloride, Hydroxyurea, Idarubicin Hydrochloride, Ifosfamide, Interferons, Interferon- α 2a, Interferon- α 2b, Interferon- α 3, Interferon- γ 1b, Interleukins, Irinotecan, Mechlorethamine hydrochloride, Melphalan, Mercaptopurine, Methotrexate, Methotrexate sodium, Mitomycin, Mitoxantrone, Mitoxantrone hydrochloride, Paclitaxel, Pegaspargase, Pentostatin, Prednimustine, Porfimer sodium, Procarbazine Hydrochloride, Taxotere, Teniposide, Topotecan Hydrochloride, Vinblastine Sulfate, Vincristine Sulfate or Vinorelbine tartrate.

47. The method of claim 22, wherein the agent is administered in combination with an anti-angiogenesis compound.

48. The method of claim 47, wherein the anti-angiogenic compound is angiostatin or endostatin.

49. The method of claim 1, wherein the agent is administered locally.

50. The method of claim 1, wherein the agent is administered systemically.

51. The method of claim 17, wherein the abnormal mammalian cell proliferation is manifested as a tumor.

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52. The method of claim 17, wherein the abnormal mammalian cell proliferation is in epithelial cells.

53. The method of claim 17, wherein the abnormal mammalian cell proliferation is selected from the group consisting of a carcinoma, a sarcoma, and a melanoma.

54. The method of claim 17, wherein the condition is a metastasis.

55. The method of claim 17, wherein the condition is selected from the group consisting of breast cancer, colorectal cancer, ovarian cancer, prostate cancer, pancreatic cancer, kidney cancer, lung cancer, melanoma and fibrosarcoma.

56. The method of claim 17, wherein the agent is administered locally.

57. The method of claim 17, wherein the agent is administered systemically.

58. The method of claim 17, wherein the subject is free of symptoms calling for hemopoietic stimulation.

59. The method of claim 17, wherein the agent is administered in combination with surgery to remove an abnormal proliferative cell mass.

60. The method of claim 17, wherein the agent is administered to a patient who has had surgery to remove an abnormal proliferative cell mass.

61. The method of claim 17, wherein the subject has normal hemopoietic activity.

62. The method of claim 17, wherein the subject is HIV negative.

63. The method of claim 17, wherein the agent is Val-boro-Pro.

64. The method of claim 17, wherein the agent is targeted to a tumor.

* * * * *